IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CHUGAI PHARMACEUTICAL CO., LTD., Plaintiff and Counterclaim Defendant, v. ALEXION PHARMACEUTICALS, INC., Defendant and Counterclaim Plaintiff.	C.A. No. 18-cv-1802-MN **JURY TRIAL DEMANDED**

ALEXION'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Alexion Pharmaceuticals, Inc., ("Alexion"), by its attorneys, hereby answers the Complaint for patent infringement ("Complaint") of Chugai Pharmaceutical Co., Ltd. ("Chugai"), in accordance with the numbered paragraphs thereof, as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), all allegations of fact and conclusions of law contained in the Complaint are denied, except those specifically admitted herein. Any factual allegation admitted herein is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. Alexion denies that Chugai is entitled to the relief requested or any other relief.

NATURE OF THE ACTION

1. Alexion admits that Chugai has brought an action for purported patent infringement and for declaratory judgment of patent infringement. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

2. Alexion admits that paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS) can be fatal, but a patient's quality of life can be improved and symptoms can be managed by medications that inhibit the C5 complement, including by medicines known as C5 inhibitors. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

3. Alexion admits that Chugai attached a copy of United States Patent No. 9,890,377 ("the '377 patent") as Exhibit 1 to the Complaint. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

4. Alexion admits that since 2007 it has marketed and continues to market an FDA-approved therapeutic antibody product known as Soliris (eculizumab). Soliris is a C5 inhibitor prescribed for patients with rare blood conditions like PNH and aHUS. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

5. Alexion admits that it submitted a BLA to the FDA seeking approval of ALXN1210, a long-acting C5 complement inhibitor and also that Alexion refers to ALXN1210 as ravulizumab and Ultomiris. Alexion denies that "[t]he ALXN1210 product incorporates Chugai's patented recycling technology." Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

6. Alexion admits that it has made its ALXN1210 product available in the U.S. in light of the FDA approval it received on or about December 21, 2018. Alexion denies any other allegations in this Paragraph of the Complaint.

7. Alexion denies the allegations in this Paragraph of the Complaint.

PARTIES

8. Alexion lacks knowledge or information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

9. Alexion lacks knowledge or information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

10. Alexion admits the allegations in this Paragraph of the Complaint.

11. Alexion admits that Soliris is a C5 inhibitor and states that Soliris had global sales of $1.6983 billion in the first half of 2018. Alexion admits that since FDA approval in 2007, Soliris has had global sales in excess of $15 billion and that Soliris accounted for 88.6% of Alexion's net product sales in 2017. Alexion denies any other allegations in this Paragraph of the Complaint.

JURISDICTION AND VENUE

12. Alexion admits that the Court has subject matter jurisdiction in this matter.

13. Alexion admits that it is incorporated in the State of Delaware.

14. Alexion admits that it is incorporated in the State of Delaware.

15. Alexion admits that this language appears in its 10-K for fiscal year 2017 at page 27.

16. Alexion admits that it owns U.S. Patent No. 6,355,245 and other U.S. patents that cover the Soliris composition and the Soliris franchise. Alexion admits that U.S. Patent No. 6,355,245 will expire in March 2021. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

17. Alexion admits that the ALXN1210 product is intended for use in patients suffering from PNH and aHUS and that Alexion has conducted at least one comparison study between the ALXN1210 product and Soliris. Alexion denies any other allegations in this Paragraph of the Complaint.

18. Alexion admits that it announced the submission of its BLA for ALXN1210 on June 19, 2018 and that it used a priority review voucher for the BLA for ALXN1210. Alexion admits that the FDA accepted the BLA for ALXN1210 and that it has a PDUFA date of February 18, 2019. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

19. Alexion admits that it has made its ALXN1210 product available in the U.S. in light of the FDA approval it received on or about December 21, 2018. Alexion admits that the transcript of the April 26, 2018 earnings call, in part, includes the language "we're formalizing and intensifying all the prelaunch commercialization plans, it's fair to anchor on the ambition which is that we want to make 1210 the new standard of care in PNH" and attributes that language to Brian Goff. Alexion admits that the transcript of the July 26, 2018 earnings call, in part, includes the language "[w]e continue to charge towards a potential launch in PNH in early 2019 and advance our ALXN1210 pipeline to pursue additional indications, as well as subcutaneous delivery options" and "[w]e're certainly ramping up in our launch preparations"

and attributes that language to Brian Goff. Alexion denies any other allegations in this Paragraph of the Complaint.

20. Alexion admits that the transcript of the October 24, 2018 call, in part, includes the language "actively preparing for anticipated launch" and attributes that language to Dr. Ludwig Hantson. Alexion admits that the transcript of the October 24, 2018 call, in part, includes the language "we anticipate the approval for 1210 here shortly in the U.S." and attributes that language to Dr. John Orloff. Alexion denies any other allegations in this Paragraph of the Complaint.

21. Alexion denies the allegations in this Paragraph of the Complaint.

THE PATENT-IN-SUIT

22. Alexion admits that the '377 patent is entitled "Antigen-Binding Molecule Capable of Binding To Two or More Antigen Molecules Repeatedly," that it lists an issue date of February 13, 2018, that it lists Chugai Seiyaku Kabushiki Kaisha as the assignee, and that it lists Tomoyuki Igawa, Shinya Ishii, Atsuhiko Maeda, and Takashi Nakai as inventors. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

23. Alexion admits that the '377 patent lists several patent applications as related U.S. patent applications or foreign priority applications, the earliest of which lists April 11, 2008 as its filing date. Alexion admits that an article titled, *Antibody Recycling by Engineered pH-Dependent Antigen Binding Improves the Duration of Antigen Neutralization* was published in *Nature Biotechnology* in 2010. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

24. Alexion denies the allegations in this Paragraph of the Complaint.

25. Alexion denies the allegations in this Paragraph of the Complaint.

26. Alexion denies the allegations in this Paragraph of the Complaint.

27. Alexion denies the allegations in this Paragraph of the Complaint.

DEFENDANT'S ALLEGED INFRINGING CONDUCT

28. Alexion denies the allegations in this Paragraph of the Complaint.

29. Alexion admits that certain information concerning ALXN1210 is recited in the '949 patent. Alexion denies any other allegations in this Paragraph of the Complaint.

30. Alexion admits that the '949 patent is entitled "Anti-C5 Antibodies Having Improved Pharmacokinetics," that the non-provisional application that resulted in the issuance of the '949 patent has a filing date of March 6, 2015, that the '949 patent issued on July 14, 2015, and that Exhibit 5 to the Complaint appears to be a copy of the '949 patent. Alexion admits that the '949 patent discusses an antibody designated as "BNJ441," and Alexion admits that the antibody designated as "BNJ441" in the '949 patent has the same primary amino acid sequence as the ALXN1210 antibody. Alexion denies any remaining allegations in this Paragraph of the Complaint.

31. Alexion admits that it filed PCT/US2017/013021, that the application was accorded an international filing date of January 11, 2017, that the application published as WO2017/123636 A1, and that WO2017/123636 A1 includes the language "[a]n exemplary anti-C5 antibody is antibody BNJ441 (also known as ALXN1210) . . . ." Alexion denies any other allegations in this Paragraph of the Complaint.

32. Alexion denies the allegations in this Paragraph of the Complaint.

33. Alexion denies the allegations in this Paragraph of the Complaint.

34. Alexion admits that it has made its ALXN1210 product available in the U.S. with the labeling approved by the FDA. Alexion denies the remaining allegations of this Paragraph of the Complaint.

35. Alexion admits that Exhibit 4 includes the following language: "Weight-optimized treatment with ALXN1210 every eight weeks demonstrated non-inferiority to treatment every two weeks with Soliris®." Alexion denies the remaining allegations of this Paragraph of the Complaint.

36. Alexion denies the allegations in this Paragraph of the Complaint.

37. Alexion admits that it was aware of the '377 patent before the instant lawsuit was filed. Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

38. Alexion admits that at some point during 2012 or 2013 at least one of its representatives participated in a meeting with representatives of Chugai. At present, Alexion lacks knowledge or information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

39. At present, Alexion lacks knowledge or information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and, therefore, denies these allegations.

40. Alexion denies the allegations in this Paragraph of the Complaint.

COUNT I — INFRINGEMENT OF THE '377 PATENT

41. Alexion incorporates each of its responses to Paragraphs 1 through 40 as if fully set forth here.

42. Alexion denies the allegations in this Paragraph of the Complaint.

43. Alexion denies the allegations in this Paragraph of the Complaint.

44. Alexion denies the allegations in this Paragraph of the Complaint.

45. Alexion denies the allegations in this Paragraph of the Complaint.

46. Alexion denies the allegations in this Paragraph of the Complaint.

COUNT II — FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '377 PATENT

47. Alexion incorporates each of its responses to Paragraphs 1 through 46 as if fully set forth here.

48. Alexion admits that it has made its ALXN1210 product available in the U.S. in light of the FDA approval it received on or about December 21, 2018. Alexion denies the remaining allegations of this Paragraph of the Complaint.

49. The allegations in this Paragraph of the Complaint are legal conclusions that require no response, and on that basis Alexion denies them.

50. Alexion denies the allegations in this Paragraph of the Complaint.

51. Alexion denies the allegations in this Paragraph of the Complaint.

52. Alexion denies the allegations in this Paragraph of the Complaint.

ANSWER TO PRAYER FOR RELIEF

Alexion denies that Chugai is entitled to any of the relief requested in paragraphs a.-f. of Chugai's prayer for relief, and further denies that Chugai is entitled to any relief or remedy whatsoever.

AFFIRMATIVE DEFENSES

Without admitting or implying that Alexion bears the burden of proof or burden of persuasion as to any of them, Alexion asserts the following affirmative defenses and other

defenses and reserves the right to amend this Answer as additional information becomes available.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

1. The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

2. Each and every claim of the '377 patent is invalid for failing to comply with one or more conditions of patentability set forth in 35 U.S.C. § 1, et. seq., including but not limited to, 35 U.S.C. §§ 101, 102, 103 and/or 112 or under other judicially-created bases for invalidation and/or unenforceability.

THIRD AFFIRMATIVE DEFENSE
(Non-Infringement)

3. Alexion has not, does not and will not infringe (including directly, indirectly, contributorily, or by inducement) any valid and enforceable claim of the '377 patent, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(Safe Harbor – 35 U.S.C. § 271(e)(1))

4. Alexion is exempt from liability under the safe harbor of 35 U.S.C. § 271(e)(1), including to the extent that Chugai claims that the manufacture and clinical use of ALXN1210 is or was an act of infringement.

FIFTH AFFIRMATIVE DEFENSE
(Prosecution-History Estoppel and Prosecution Disclaimer)

5. Chugai claims are barred, in whole or in part, by representations or actions taken during the prosecution of the '377 patent, and related patents or patent applications under the doctrine of prosecution-history estoppel and/or prosecution disclaimer.

SIXTH AFFIRMATIVE DEFENSE
(No Willfulness)

6. Alexion has not willfully infringed any claim of the '377 patent.

SEVENTH AFFIRMATIVE DEFENSE
(No Recovery of Costs)

7. Chugai is not entitled to seek recovery of costs pursuant to 35 U.S.C. § 288.

EIGHTH AFFIRMATIVE DEFENSE
(Exceptional Case)

8. Alexion's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285. But Chugai's action in bringing and maintaining this case is exceptional under 35 U.S.C. § 285. Alexion is entitled to an award of its attorneys' fees incurred in connection with defending and prosecuting this action.

NINETH AFFIRMATIVE DEFENSE
(Lack of Standing)

9. Chugai lacks standing to assert the '377 patent.

OTHER AFFIRMATIVE DEFENSES RESERVED

As Alexion's investigation is ongoing and discovery is not yet completed, Alexion is without complete information regarding the existence or non-existence of other facts or acts that would constitute a defense to the purported causes of action in the Complaint. Accordingly, Alexion reserves the right to assert any other defenses that discovery may reveal or that Alexion otherwise becomes aware of at a future time.

COUNTERCLAIMS

Defendant and Counterclaim Plaintiff Alexion Pharmaceuticals, Inc. submits these counterclaims against Plaintiff and Counterclaim Defendant Chugai Pharmaceutical Co., Ltd.

THE PARTIES

1. Counterclaim Plaintiff Alexion is a company organized and existing under the laws of the State of Delaware with its corporate headquarters at 121 Seaport Blvd., Boston, Massachusetts 02210.

2. Upon information and belief, Counterclaim Defendant Chugai is based in Japan with a head office at 1-1 Nihonbashi-Muromachi 2-chrome, Nihonbashi Tower Chuo-ku, Tokyo 103-8324 Japan. Chugai has a United States subsidiary corporation named Chugai Pharma USA, Inc., that has an office at 3000 Connell Drive, Suite 3100, Berkley Heights, NJ 07922.

JURISDICTION AND VENUE

3. Alexion's counterclaims arise under the patent laws of the United States, Title 35 of the United States Code, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction over Alexion's counterclaims under 28 U.S.C. §§ 1331 and 1338.

4. The Court has personal jurisdiction over Chugai because Chugai personally availed itself of this Court's jurisdiction by filing its Complaint in this District, and Alexion's counterclaims arise from the Complaint that Chugai filed in this District.

5. Venue in this case is proper in this District because Chugai filed its Complaint in this District and that action gives rise to Alexion's counterclaims. Chugai contends in the Complaint that venue is proper in this District.

FACTUAL BACKGROUND

Alexion and the Development of the First Approved Terminal Complement Inhibitor

6. Founded in 1992, Alexion is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the discovery, development and commercialization of life-changing therapies. Alexion focuses its research on biologic drugs.

Biologic drugs are "complex mixtures that are not easily identified or characterized." "Biological products often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available." *See* FDA, What are "Biologics" Questions and Answers at https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm. Due to their complex nature, biologic drugs often require substantially more effort, monetary resources and technical expertise to develop compared to a drug that is synthesized chemically.

7. Alexion's focus on developing treatments for rare diseases allowed it to develop Soliris® (eculizumab), the world's first approved terminal complement inhibitor, for the treatment of patients with paroxysmal nocturnal hemoglobinura (PNH), atypical uremic syndrome (aHUS), and anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG). Through its research and development efforts, in 2007 Alexion received approval of Soliris by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as the first and only treatment for patients with PNH. In 2008 Soliris received the Prix Galien USA Award for the Best Biotechnology Product. In 2009 Soliris received the Prix Galien France Award for Drugs for Rare Diseases. In 2011 the FDA approved Soliris for the treatment of aHUS, and in 2017 the FDA approved Soliris for the treatment of anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG).

8. The complement system provides critical immunoprotective and immunoregulatory functions, but uncontrolled complement activation can lead to severe hemolytic diseases, including PNH. Alexion undertook to develop an antibody that targets the

C5 protein that is part of the terminal complement system of the human immune system. By targeting C5, Alexion was able to block the proinflammatory and cytolytic effects of terminal complement activation, while maintaining the critical immunoprotective and immunoregulatory functions of the upstream proximal complement system.

9. The C5 protein is cleaved by C5 convertase into C5a and C5b fragments. C5a mediates signals in a variety of cell types, while C5b recruits the terminal complement components C6, C7, C8, and C9 to form the terminal complement complex (TCC) or membrane attached complex (MAC) on the surface of cells. The generation of TCC stimulates the release of proinflammatory molecules. The unimpeded assembly of TCC on cell surfaces results in cell lysis. Deposition of TCC on erythrocytes results in the destruction of these cells in hemolytic diseases such as PNH.

10. In developing eculizumab, Alexion generated a panel of potential murine anti-human C5 monoclonal antibodies and screened the antibodies for their ability to inhibit TCC-mediated lysis of antibody-sensitized chicken erythrocytes by human complement in a standard hemolytic assay. The process involved screening about 30,000 hybridomas. The screening identified one murine monoclonal antibody that was effective at blocking both TCC-mediated hemolysis and the generation of C5a, at a 0.5:1 molar ratio of antibody to C5.

11. Alexion cloned the complementarity-determining regions of the identified murine monoclonal antibody. In order to reduce immunogenicity of the antibody, Alexion humanized the murine monoclonal antibody by grafting the cloned complementarity-determining regions into human heavy and light chain antibody frameworks. Alexion also engineered the CH1-hinge-CH2-CH3 regions of the heavy chain to give the antibody even further advantageous properties. This humanized monoclonal anti-C5 antibody later become known as “eculizumb.”

Chugai's Attempt to Develop Its Own Terminal Complement Inhibitor

12. Several Chugai employees, including at least three of the inventors listed on the '377 patent, Tomoyuki Igawa, Shinya Ishii and Atsuhiko Maeda, have been involved in Chugai's attempt to develop its own C5 complement inhibitor, SKY59. These inventors have acknowledged that "eculizumab, an anti-complement C5 monoclonal antibody, is the current standard of care for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS)." *See* Exhibit A to Answer, Affirmative Defenses and Counterclaims, at 1 (Abstract).

13. Upon information and belief, during the development of SKY59, Chugai employees, including at least Yoshinao Ruike and Zenjiro Sampei, tested eculizumab and determined the equilibrium dissociation constant (KD) of eculizumab under different pH conditions. These Chugai employees reported the determined KD values for eculizumab in United States Patent Application No. 14/974,350 filed on December 18, 2015. This application issued as US Pat. No. 9,765,135 ("the '135 patent"). Exhibit B to Answer, Affirmative Defenses and Counterclaims.

14. The '135 patent discloses that the KD values for eculizumab at pH 5.8 and pH 7.4 are measured using a BIACORE T200 instrument. See Exhibit B, col. 79, lns. 17-54. The '135 patent discloses that eculizumab has a ratio of KD at pH 5.8/pH7.4 for eculizumab of 19. *Id*. at column 79, Table 10 This KD ratio falls within the KD ranges recited in, at least, claims 1 and 7 of the '377 patent.

15. Upon information and belief, the antibody designated as SKY59 is referenced by other identifiers, including RG6107 and RO7112689. RO7112689 is currently in a Phase I/II study entitled "An Adaptive Phase I/II Study to Assess Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of RO71125689 in Healthy Volunteers and Patients with Paroxysmal

Nocturnal Hemoglobinuria (PNH)." Upon information and belief, Chugai Pharmaceutical Co., Ltd is not the Phase I/II study sponsor. Upon information and belief, Hoffman-La Roche is the study sponsor. Upon information and belief, the study started November 14, 2016 and has an estimated primary completion date and a study completion date of January 30, 2021. Upon information and belief, a Phase III clinical trial will be required before submission of a BLA to the FDA seeking approval to commercialize RO7112689 for the treatment of PNH.

THE PATENT-IN-SUIT

16. United States Patent No. 9,890,377, titled "Antigen-Binding Molecule Capable of Binding to Two or More Antigen Molecule Repeatedly," issued on February 13, 2018. The '377 patent identifies Chugai Seiyaku Kabushiki Kaisha as the assignee. *See* D.I. 1-1.

17. The '377 patent includes descriptions of various prior art publications. One of the prior art publications described is Ito et al., "The His-probe method: effects of histidine residues introduced into complementarity-determining regions of antibodies on antigen-antibody interactions at different pH values," FEBS Lett., 309:85-88 (1992). D.I. 1-1, at col. 12, lns. 63-66; col. 58, lns. 60-66; and col. 59, lns. 49-52. The '377 patent acknowledges that the listed inventors of the '377 patent were not the first to modify the variable region of an antibody such that the pH condition would affect the binding between the antibody and the antigen.

18. The '377 patent includes the following statement: "It is already known that an antibody can be conferred with a pH-dependent antigen-binding activity by substituting histidine for amino acids in the antibody (FEBS Letter, 309(1), 8588 (1992))." D.I. 1-1, at col. 12, lns. 63-66.

19. The '377 patent includes the following statement: "pH-dependence can be imparted to protein-protein interactions by substituting an amino acid residue involved in protein-protein interactions with a histidine residue, or by introducing a histidine into an

interaction site. Such attempts have also been made in protein-protein interactions between antibodies and antigens, and a mutant antibody with antigen-binding ability decreased under acidic conditions has been successfully acquired by introducing histidine into the CDR sequence of an anti-egg white lysozyme antibody (FEBS Letter (vol. 309, No. 1, 85-88, 1992)).” D.I. 1-1, at col. 58, lns. 56-66.

20. The ’377 patent includes the following statement: “Introduction of histidine into a CDR has been reported as a method for introducing pH-dependent binding to antigen-antibody reaction (FEBS Letter (col. 309, No. 1, 85-88, 1992)).” D.I. 1-1, col. 59, lns. 49-52.

21. The ’377 patent specification as filed includes a general discussion of antibodies that can bind to various membrane-bound or soluble antigens. The ’377 patent specification as filed includes examples of “membrane antigens such as cell surface markers, and soluble antigens such as cytokines” which “antigen-binding molecules of the present invention may recognize.” D.I. 1-1, at col. 31, lns. 5-17, *see also* col. 24, lns. 21-43. The ’377 patent specification as filed provides examples of antibodies that bind to the IL-6 receptor antigen and the IL-31 receptor antigen.

22. The ’377 patent specification as filed does not identify the C5 antigen anywhere in the specification. The ’377 patent specification as filed does not provide any data concerning an antibody that binds to the C5 antigen.

23. The ’377 patent includes 24 claims. Certain of those claims appear to require modification of the variable region of at least one antibody by the substitution or insertion of at least one histidine into the variable region of that antibody. Other claims of the ’377 patent do not appear to require any modification of the variable region of an antibody.

24. Chugai alleges that it owns the ’377 patent.

25. A case or controversy exists because Chugai alleges that Alexion has infringed or will infringe one or more claims of the '377 patent.

Count 1
Invalidity of United States Patent No. 9,890,377

26. Alexion restates and incorporates by reference the allegations in paragraphs 1 to 25 as if fully set forth herein.

27. The claims of the '377 patent are invalid for failing to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the following reasons:

- Under § 101, because the '377 patent includes claims, e.g., at least claims 1-10, that are directed to patent-ineligible concepts by claiming a natural property of certain antibodies that have different equilibrium dissociation constants under different pH conditions and that the additional elements of the claim do not transform the claim into a patent-eligible application;

- Under § 102, because the '377 patent includes claims, e.g., at least claims 1-4 and 7, with claim scopes that encompass prior art antibodies, e.g., eculizumab, which, upon information and belief, possess the KD ratio claimed and were administered to patients in need of having an antigen removed from their plasma;

- Under § 103, because the claims of the '377 patent would have been obvious to a person of ordinary skill in the art based upon prior art references, including, but not limited to, Ito et al., "The His-probe method: effects of histidine residues introduced into complementarity-determining regions of antibodies on antigen-antibody interactions at different pH values," FEBS Lett., 309:85-88 (1992).

- Under § 112, because the specification fails to enable the full scope of the claims of the '377 patent and fails to show that the inventors were in possession of the purported inventions recited in each claim. Considering the breadth of the claims, it would have taken undue experimentation to identify antibodies that fall within the scope of the claims and/or the specification fails to disclose a representative number of species falling within the scope of the claimed genus or structural features common to the members of the claimed genus so that one of skill in the art could have visualized or recognized the members of the genus.

28. Alexion is entitled to judgment that the claims of the '377 patent are invalid and/or unenforceable, for at least the reasons set forth above. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 2
Non-Infringement of United States No. 9,890,377

29. Alexion restates and incorporates by reference the allegations in paragraphs 1 to 28 as if fully set forth herein.

30. Alexion has not, does not, and will not infringe any valid claim of the '377 patent, at least for the reasons recited in paragraph 27. Moreover, Alexion does not infringe several of the claims of the patents because it has not performed or encouraged the performance of each step of the claimed method after the issuance of the patent. For example, Alexion identified ALXN1210 before the issuance of the '377 patent.

31. Alexion is entitled to judgment that it has not, does not and will not infringe any valid claim of the '377 patent, for at least the reasons set forth above. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

JURY DEMAND

Alexion hereby respectfully demands a jury trial of all issues triable to a jury in this action.

PRAYER FOR RELIEF

WHEREFORE, Alexion respectfully requests that the Court enter judgment:

A. adjudging and decreeing that Chugai be denied all forms of relief requested in its Complaint;

B. dismissing the Complaint in its entirety with prejudice;

C. declaring that Alexion has not and will not either directly or indirectly infringe the claims of the ’377 patent;

D. declaring the claims of the ’377 patent are invalid;

E. finding that this is an exceptional case under 35 U.S.C. § 285;

F. awarding attorneys’ fees, costs, and expenses to Alexion; and

G. granting such other and further relief as this Court deems just and proper.

Dated: January 4, 2019

Respectfully submitted,

FARNAN LLP

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